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7/2/03**FAX RECEIVED**JUN 30 2003**FAX TRANSMISSION****GROUP 1600****OFFICIAL****DATE:** June 27, 2003**PTO IDENTIFIER:** Application Number 09/689,430  
Patent Number**Inventor:** WALSH et al.**MESSAGE TO:** Examiner Q. Janice Li - Group Art Unit 1632**FAX NUMBER:** (703) 872-9306**FROM:** CONNOLLY BOVE LODGE & HUTZ LLP  
Burton A. Amernick**PHONE:** (202) 331-7111**Attorney Dkt. #:****PAGES (Including Cover Sheet):** 3**CONTENTS:** 

If your receipt of this transmission is in error, please notify this firm immediately by collect call to (202) 331-7111 and send the original transmission to us by return mail at the address below.

**CONNOLLY BOVE LODGE & HUTZ LLP**  
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Telephone: (202) 331-7111 Facsimile: (202) 293-6229

PTO/SB/97 (12-97)

Approved for use through 9/30/00. OMB 0651-0031

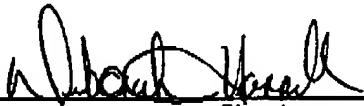
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Deborah A. Harrell  
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Communication To The Examiner

JUN-27-2003 15:13

CONNOLLY BOVE LODGE & HUTZ

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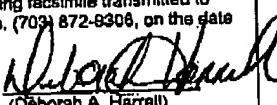
Continuation Sheet (PTO-413)

Application No. 09/689,430

Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: The rejection under 112, 1st paragraph may be withdrawn in view of the claim amendments and the evidence provided in the specification and IDS. With regards to rejection under section 103, applicants indicated that the amended claims are limited to an rAAV vector consisting of the AAV ITR promoter, and using the AAV ITR promoter is a surprise finding, because factor VIII is considered a peptide difficult to be expressed at high level and AAV ITR is a weak promoter. The Examiners indicated that claims as written do not require the levels of expression, thus, the rejection stands.

I hereby certify that this correspondence is being facsimile transmitted to the Patent and Trademark Office, facsimile no. (703) 672-8306, on the date shown below.

Dated: 6/27/03

Signature:   
(Deborah A. Harrell)

Docket No.: 21095-00004-US

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:  
**WALSH et al.**

Application No.: 09/689,430

Group Art Unit: 1632

Filed: Unknown

Examiner: Q. Janice Li

For: UNKNOWN....

**COMMUNICATION TO THE EXAMINER**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

The undersigned attorney received the attached Interview Summary form PTO-413 in connection with the above-identified application. Our records indicate that this application is not assigned to our firm, Connolly Bove Lodge & Hutz LLP.

As a follow-up to a telephone discussion with the Examiner, we are returning the Interview Summary relating to another application that was inadvertently sent to our firm.

Dated: June 27, 2003

Respectfully submitted,

By   
Burton A. Amernick, Reg. No. 24,852  
CONNOLLY BOVE LODGE & HUTZ LLP  
1990 M Street, N.W., Suite 800  
Washington, DC 20036-3425  
(202) 331-7111  
(202) 293-6229 (Fax)  
Attorney for Applicant

<b>Interview Summary</b>	<b>Application N .</b>	<b>Applicant(s)</b>	
	09/689,430	WALSH ET AL.	

<b>Examiner</b>	<b>Art Unit</b>	
Q. Janice Li	1632	

All participants (applicant, applicant's representative, PTO personnel):

- (1) Q. Janice Li, PTO. (3) Murray Spruill, Kathryn Coulter, Appl. Rep.  
 (2) Anne Marie Wehbe, PTO. (4) Kim Clary, Scientist at Gene targeting Inc.

Date of interview: 01 March 0703.

Type: a) Telephonic b) Video Conference  
 c) Personal [copy given to: 1) applicant 2) applicant's representative]

Exhibit shown or demonstration conducted: d) Yes e) No.  
 If Yes, brief description: draft for amendments and response.

Claim(s) discussed: 1-20 and 58-90.

Identification of prior art discussed: Dwarki, Pitman, Gritsenko.

Agreement with respect to the claims f) was reached. g) was not reached. h) N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: See Continuation Sheet.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

  
 Examiner's signature, if required



UNITED STATES  
PATENT AND  
TRADEMARK OFFICE

FEB 20 2003

Commissioner for Patents  
Washington, DC 20231  
[www.uspto.gov](http://www.uspto.gov)

Dear Patent Business Customer:

The United States Patent and Trademark Office ("Office") is now permitting and encouraging applicants to voluntarily submit amendments in a revised format as set forth in *AMENDMENTS IN A REVISED FORMAT NOW PERMITTED*, *Off. Gaz. Pat. Office* (February 25, 2003), currently available on the USPTO web site at <http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/revamdtprac.htm>. The revised format permits amendments to the specification and claims to be made in a single marked-up version; the requirement for a clean version is eliminated. Attached, you will find a flyer with information and instructions regarding the procedures to be used to comply with the revised format. The flyers are being inserted with out-going Office actions mailed during the period of February 20, 2003 - March 31, 2003.

The revised amendment format is essentially the same as the amendment format for the specification, claims, and drawings that the Office is considering adopting via a revision to 37 CFR 1.121 (Manner of Making Amendments). The revision to 37 CFR 1.121 (if adopted) will simplify amendment submission and improve file management. This proposed revision and others necessary to facilitate a gradual transition to the use of an Electronic File Wrapper (EFW) will be set forth in a Notice of Proposed Rule making (NPR), expected to be published by March 2003. After consideration of public comments, the Office anticipates adopting a revision to § 1.121, following publication of a Notice of Final Rule making (NFR), expected by June 2003, at which point compliance with revised § 1.121 will be mandatory.

The Office will continue to accept your amendment submissions in the revised format during the voluntary period, which will extend up to the effective date of final revisions to § 1.121. The Office also encourages your feedback on the proposed revised amendment format and other changes set forth in the NPR, expected to be published by March 2003.

For assistance: Any questions regarding the submission of amendments pursuant to the revised practice should be directed to Office of Patent Legal Administration (OPLA), Legal Advisors Elizabeth Dougherty ([Elizabeth.Dougherty@uspto.gov](mailto:Elizabeth.Dougherty@uspto.gov)), Gena Jones ([Eugenia.Jones@uspto.gov](mailto:Eugenia.Jones@uspto.gov)) or Joe Narcavage ([Joseph.Narcavage@uspto.gov](mailto:Joseph.Narcavage@uspto.gov)). Alternately, you may send e-mail to "Patent Practice", the OPLA e-mail address that has been established for receiving queries and questions about patent practice and procedures or telephone OPLA at (703) 305-1616.

A handwritten signature in black ink, appearing to read "Nicholas P. Godici".

Nicholas P. Godici  
Commissioner for Patents

Attachment: Flyer entitled: *Revised Notice\* AMENDMENTS MAY NOW BE SUBMITTED IN REVISED FORMAT*

## AMENDMENTS MAY NOW BE SUBMITTED IN REVISED FORMAT

The United States Patent and Trademark Office (USPTO) is permitting applicants to submit amendments in a revised format as set forth below. Further details of this practice are described in **AMENDMENTS IN A REVISED FORMAT NOW PERMITTED**, signed January 31, 2003, expected to be published in *Official Gazette* on February 25, 2003 (Notice posted on the Office's web site at <http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/revamdtprac.htm>). The revised amendment format is essentially the same as the amendment format that the Office is considering adopting via a revision to 37 CFR 1.121 (Manner of Making Amendments). The revision to 37 CFR 1.121 (if adopted) will simplify amendment submission and improve file management. The Office plans to adopt such a revision to 37 CFR 1.121 by July of 2003, at which point compliance with revised 37 CFR 1.121 will be mandatory.

Effective immediately, all applicants may submit amendments in reply to Office actions using the following format. Participants in the Office's electronic file wrapper prototype<sup>1</sup> receiving earlier notices of the revised practice may also employ the procedures set out below.

### REVISED FORMAT OF AMENDMENTS

**Begin on separate sheets:**

Each section of an Amendment (e.g., Claim Amendments, Specification Amendments, Drawing Amendments, and Remarks) should begin on a separate sheet. *For example*, in an amendment containing a.) introductory comments, b.) amendments to the claims, c.) amendments to the specification, and d.) remarks, each of these sections must begin on a separate sheet. This will facilitate the process of separately indexing and scanning of each part of an amendment document for placement in an electronic file wrapper.

**Two versions of amended part(s) no longer required:**

The current requirement in 37 CFR 1.121(b) and (c) to provide two versions (a clean version and a marked up version) of each replacement paragraph, section or claim will be waived where an amendment is submitted in revised format below. The requirements for substitute specifications under 37 CFR 1.125 will be retained.

**A) Amendments to the claims:**

Each amendment document that includes a change to an existing claim, or submission of a new claim, must include a complete listing of all claims in the application. After each claim number, the status must be indicated in a parenthetical expression, and the text of each claim under examination (with markings to show current changes) must be presented. The listing will serve to replace all prior versions of the claims in the application.

- (1) The current status of all of the claims in the application, including any previously canceled or withdrawn claims, must be given. Status is indicated in a parenthetical expression following the claim number by one of the following: (original), (currently amended), (previously amended), (canceled), (withdrawn), (new), (previously added), (reinstated - formerly claim #\_), (previously reinstated), (re-presented - formerly dependent claim #\_), or (previously re-presented). The text of all pending claims under examination must be submitted each time any claim is amended. Canceled and withdrawn claims should be indicated by only the claim number and status.
- (2) All claims being currently amended must be presented with markings to indicate the changes that have been made relative to the immediate prior version. The changes in any amended claim should be shown by strikethrough (for deleted matter) or underlining (for added matter). An accompanying clean version is not required and should not be presented. Only claims of the status "currently amended" will include markings.
- (3) The text of pending claims not being amended must be presented in clean version, i.e., without any markings. Any claim text presented in clean version will constitute an assertion that it has not been changed relative to the immediate prior version.

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<sup>1</sup> The Office's Electronic File Wrapper prototype program is described in *USPTO ANNOUNCES PROTOTYPE OF IMAGE PROCESSING*, 1265 Off. Gaz. Pat. Office 87 (Dec. 17, 2002) ("Prototype Announcement"), and applies only to Art Units 1634, 2827 and 2834.

- (4) A claim may be canceled by merely providing an instruction to cancel. Listing a claim as canceled or withdrawn shall not constitute an instruction to cancel. Any claims added by amendment must be indicated as (new) and shall not be underlined.
- (5) All of the claims in each amendment paper must be presented in ascending numerical order. Consecutive canceled or withdrawn claims may be aggregated into one statement (e.g., Claims 1 - 5 (canceled)).

Example of listing of claims (use of the word "claim" before the claim number is optional):

Claims 1-5 (canceled)

Claim 6 (withdrawn)

Claim 7 (previously amended): A bucket with a handle.

Claim 8 (currently amended): A bucket with a ~~green~~ blue handle.

Claim 9 (withdrawn)

Claim 10 (original): The bucket of claim 8 with a wooden handle.

Claim 11 (canceled)

Claim 12 (re-presented – formerly dependent claim 11) A black bucket with a wooden handle.

Claim 13 (previously added): A bucket having a circumferential upper lip.

Claim 14 (new): A bucket with plastic sides and bottom.

**B) Amendments to the specification:**

Amendments to the specification must be made by presenting a replacement paragraph or section marked up to show changes made relative to the immediate prior version. An accompanying clean version is not required and should not be presented. If a substitute specification is being submitted to incorporate extensive amendments, both a clean version (which will be entered) and a marked up version must be submitted as per current 37 CFR 1.125.

**C) Amendments to drawing figures:**

Drawing changes must be made by presenting replacement figures which incorporate the desired changes and which comply with § 1.84. An explanation of the changes made must be presented in the remarks section of the amendment. Any replacement drawing sheet must include all of the figures appearing on the immediate prior version of the sheet, even though only one figure may be amended. The figure or figure number of the amended drawing should not be labeled as "amended." If the changes to the drawing figure(s) are not accepted by the examiner, applicant will be notified of any required corrective action in the next Office action. No further drawing submission will be required, unless applicant is notified.

Any questions regarding the submission of amendments pursuant to the revised practice set forth in this flyer should be directed to the following legal advisors in the Office of Patent Legal Administration (OPLA): Elizabeth Dougherty ([Elizabeth.Dougherty@uspto.gov](mailto:Elizabeth.Dougherty@uspto.gov)), Gena Jones ([Eugenia.Jones@uspto.gov](mailto:Eugenia.Jones@uspto.gov)) or Joe Narcavage ([Joseph.Narcavage@uspto.gov](mailto:Joseph.Narcavage@uspto.gov)). For information on the waiver or legal aspects of the prototype, please contact Jay Lucas ([Jay.Lucas@uspto.gov](mailto:Jay.Lucas@uspto.gov)), Senior Legal Advisor (PCTLA) or Rob Clarke ([Robert.Clarke@uspto.gov](mailto:Robert.Clarke@uspto.gov)), Senior Legal Advisor (OPLA). Alternatively, further information may be obtained by calling OPLA at (703) 305-1616.

\* Revised Notice: See Sec. B) for changes relating to substitute specifications, and Sec. C) for changes on replacement drawing practice.

Flyer for mailing with all Office actions by all TCs (except Art Units 1634, 2827 and 2834)  
02/13/03